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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,287	10/01/2003	Richard Hochberg	Y03-076US	7077

7590 01/06/2010

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
01/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,287	HOCHBERG, RICHARD	
	Examiner	Art Unit	
	Barbara P. Badio	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 39-73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 39-73 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 13, 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The rejection of claims 57-64 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant argues the limitation is directed to reducing the likelihood of a recurrence and does not imply that a treated patient would necessarily relapse absent treatment. According to applicant, the skilled artisan in the art as of the filing date, knew risk of relapse implicated factors such as diet, estrogen levels, estrogen metabolites and the existence of precancerous tissue by biopsy. Applicant's argument was considered but not persuasive for the following reason.

As noted by applicant, (a) there are several factors that are considered risk factors for relapse and (b) reducing the likelihood of recurrence does not imply the treated patient would necessarily relapse absent treatment. In essence, the presence

of said risk factor(s) does not imply relapse would necessary occur. Thus, the skilled artisan would have to be able to determine patients with said risk factors in which relapse would occur that would be in need of treatment in order to reduce said occurrence. The present specification does not provide any description as to how the skilled artisan in the art at the time of the present invention would make said determination.

For this reason and those given in the previous Office Actions, the rejection of claims 57-64 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

3. The rejection of claims 39, 42, 65, 67, 68 and 70-73 under 35 USC 112, first paragraph, scope of enablement is withdrawn.

4. Claims 48-51 and 65-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite "wherein administration of the SERM does not exacerbate symptoms of the cancer and reduces the risk that the patient develops another estrogen-sensitive cancer". Applicant did not point to and the examiner was

unable to find where support for said limitation is found in the present specification. Thus, the above-mentioned phrase is considered new matter.

5. The rejection of claims 57-64 under 35 USC 112, second paragraph is withdrawn.

6. Claims 39-47, 52-56 and 65-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite "cardiovascular disease associated with elevated cholesterol or elevated low-density lipoproteins (LDL)" without identification of any disease(s). Absence identification cardiovascular diseases encompassed by the phrase, the skilled artisan would be unable to determine the metes and bound of the claimed invention.

Claim Rejections - 35 USC § 103

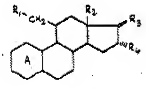
7. The rejection of claims 39-56 and 65-73 under 35 USC 103(a) over Van den Broek et al. (US 3,972,906) is maintained.

Applicant argues the compounds of Van den Broek are estrogenic in the liver and in promoting bone growth whereas the compounds used in the claimed methods of treatment are antiestrogenic in the uterus, breast and vaginal. Applicant also argues that there was no recognition in the prior art that synthetic steroid could in fact treat

menopausal symptoms while lowering cancer risk and without exacerbating preexisting cancer symptoms nor an understanding that said compounds could treat an estrogen-sensitive cancer or reduce the likelihood of a reoccurence of breast cancer. Applicant's argument was considered but not persuasive for the following reason.

The issue is not whether the art recognized the differences in the action of the compounds in different target organs. The issue is whether the art teaches or suggest the use of the compounds as claimed by the instant invention.

Claims 39 and 65 are directed to treating menopausal symptoms such as osteoporosis (see instant claims 40 and 66, respectively) and claim 48 is directed to treating an estrogen-sensitive cancer such as breast cancer (see instant claim 49). Van den Broek teaches 11-substituted steroids such as 11-alkoxymethyl substituted steroids of the estrane series of the formula:



wherein R_1 is a free, esterified or etherified hydroxyl group, inclusive of 11β-methoxymethyl-ethinyl-estradiol, for use in the treatment of estrogen-deficiency syndromes (see the entire article, especially col. 1, line 60 – col. 2, line 53).

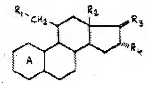
Van den Broek does not set forth any specific estrogen-deficiency syndrome(s). However, in the medical art, estrogen-deficiency syndromes are inclusive of osteoporosis, breast cancer, atherosclerosis (cardiovascular disease caused by elevated cholesterol). References were provided in previous Office Actions.

Based on the teaching of Van den Broek and the level of skill of the ordinary artisan in the art as it relates to estrogen-deficiency syndromes, the examiner maintains the claimed invention is prima facie obvious.

Additionally, applicant's argument(s) as noted above is not persuasive because a compound and its properties are not separable. As recognized by MPEP §2112, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Genva Pharm. Inc.* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). The prior art compound(s) utilized as taught by Van den Broek would inherently reduce the risk that the patient develops an estrogen-sensitive cancer or another cancer as well not exacerbate symptoms of cancer because identical compounds would be expected to have identical properties.

8. Claims 39-56 and 65-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broek et al. (US 3,972,906) in view of Cameron et al. (US 2001/0025051), Palkowitz (US 6,268,361) and Bodor et al. (US 4,617,298).

Van den Broek teaches 11-substituted steroids such as 11-alkoxymethyl substituted steroids of the estrane series of the formula:



wherein R_1 is a free, esterified or etherified hydroxyl group, inclusive of 11β-methoxymethyl-ethinyl-estradiol, for use in the treatment of estrogen-deficiency syndromes (see the entire article, especially col. 1, line 60 – col. 2, line 53). The reference teaches preparation of various formulations such as tablets, solutions and suspensions (see col. 7, lines 3-18).

The instant claims differ from the reference by reciting the treatment of "the symptomology of menopause" (claims 39 and 65) and "estrogen-sensitive cancer" (claim 48). However, the use of estrogen in the treatment of menopausal symptoms, osteoporosis as well as treating estrogen-dependent cancer such as breast cancer is well known in the medical art (see for example, **US 2001/0025051**, section 003; US **6,268,361**, Abstract; **US 4,617,298**, col. 3, lines 25-31). Therefore, the use of the compounds of Van den Broek in treating the symptoms of menopause, such as osteoporosis (claims 39-47, 52-56 and 65-73) and estrogen-sensitive cancer such as breast cancer (claims 48-51) would have been obvious to the skilled artisan in the art at the time of the present invention based on the teaching of Van den Broek of the utilization of the prior art compound for treatment of estrogen-deficiency syndromes such as menopausal symptoms, osteoporosis and estrogen-dependent cancer, for example, breast cancer.

The instant claims further differ from the reference by reciting "while reducing the risk that the patient develops an estrogen-sensitive cancer" (claim 39); "wherein administration of the SERM does not exacerbate symptoms of the cancer and reduces the risk that the patient develops another estrogen-sensitive cancer" (claims 48 and 65). However, as recognized by MPEP §2112, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Genva Pharm. Inc.* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). The prior art compound(s) utilized as taught by Van den Broek would inherently reduce the risk that the patient develops an estrogen-sensitive cancer or another cancer as well not exacerbate symptoms of the cancer because identical compounds would be expected to have identical properties. One can not separate a compound and its properties.

Lastly, claim 65 differs from the reference by reciting the treatment of the symptoms of menopause in "a patient suffering from an estrogen-sensitive cancer". As noted above, the art teaches the use of estrogens in the treatment of both symptoms of menopause and estrogen-sensitive cancer. Thus, the use of the compounds of Van den Broek useful in treating estrogen-deficiency syndromes, inclusive of symptoms of menopause and estrogen-sensitive cancer, would have been obvious to the skilled artisan in the art at the time of the present invention. Additionally, the use of estrogen in treatment of the symptoms of menopause is inclusive of all menopausal patients such as those suffering from an estrogen-sensitive cancer and, thus, the skilled artisan would

have the reasonable expectation that the compounds of Van den Broek would be useful in treating symptoms of menopause in patients suffering from an estrogen-sensitive cancer.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628